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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,712	07/09/1999	CHI-HUEY WONG	TSRI482.1	6395

7590 06/28/2002

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EXAMINER
FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 06/28/2002 16

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/077,712	WONG ET AL.	
Examiner	**Art Unit**	
Tomas Friend	1627	

Office Action Summary

file copy

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

A response to a notice to comply with sequence rules with CRF disk and preliminary amendment was received on 30 April 2002 (Paper No. 15).

Status of the Claims

Claims 1-18 are pending and subject to restriction and election of species requirements.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

1. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, drawn to a method of identifying a drug candidate as an HIV protease inhibitor.

Group II, claim(s) 2, drawn to a method of synthesizing a drug candidate for inhibiting HIV protease.

Group III, claim(s) 3, drawn to a method for synthesizing a library of nxm drug candidates for inhibiting HIV protease including an α-keto amid core structure.

Group IV, claim(s) 4, drawn to a method for synthesizing a library of nxm drug candidates for inhibiting HIV protease including a hydroxyethylamine core structure.

Group V, claim(s) 5, drawn to a library of nxm drug candidates for inhibiting HIV protease including an α-keto amid core structure.

Group VI, claim(s) 6, drawn to a library of nxm drug candidates for inhibiting HIV protease including a hydroxyethylamine core structure.

Group VII, claim(s) 7 and 8, drawn to an improved mechanism based inhibitor of HIV or FIV aspartyl protease having an α-keto amid core structure and a C-terminus including a pyrrolidine heterocyclic ring.

Group VIII, claim(s) 9 and 10, drawn to an improved mechanism based inhibitor of HIV or FIV aspartyl protease having an α-keto amid core structure and a C-terminus including a piperadine or an azasugar heterocyclic ring.

Group IX, claim(s) 11 and 12, drawn to an improved mechanism based inhibitor of HIV or FIV aspartyl protease having an α-keto amid core structure and a C-terminus including a tyrosine or phenylalanine.

Group X, claim(s) 13 and 14, drawn to an improved mechanism based inhibitor of HIV or FIV aspartyl protease having a hydroxyethylamine core structure and a C-terminus including a pyrrolidine heterocyclic ring.

Group XI, claim(s) 15 and 16, drawn to an improved mechanism based inhibitor of HIV or FIV aspartyl protease having a hydroxyethylamine core structure and a C-terminus including a piperadine or an azasugar heterocyclic ring.

Group XII, claim(s) 17 and 18, drawn to an improved mechanism based inhibitor of HIV or FIV aspartyl protease having a hydroxyethylamine core structure and a C-terminus including a tyrosine or phenylalanine.

2. The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Group I, Group II, Groups III, V, VII, VIII, IX, and Groups IV, VI, X, XI, and XII lack a corresponding special technical feature. The special technical feature of Group I appears to be a system for screening protease inhibitors. The special technical feature of Group II appears to be a system for synthesizing protease inhibitors.

The inventions of Groups III, V, VII, VIII, IX appear to share the corresponding special technical feature of an α-keto amid core structure which is shown by OCAIN et al. (1992) J. Med. Chem. Vol. 35:451-456 to lack novelty and is not a contribution over the prior art.

The inventions of Groups IV, VI, X, XI, and XII appear to share the corresponding special technical feature of a hydroxyethylamine core structure which is shown by DEBOUCK (1992) AIDS Research and Human Retroviruses Vol. 8(2):153-164 to lack novelty and is not a contribution over the prior art. DEBOUCK discloses protease inhibitors with a hydroxyethylamine core structure on page 157, column 1.

3. Because these inventions are distinct for the reasons given above and

a. have acquired a separate status in the art;
b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
c. have divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

Election of Species

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If applicant elects one of Group II or III, applicant is required to elect a species for each of the following categories such that all of the species are compatible with one another:

A. ultimate species (i.e. structure drawing) of drug candidate,

B. species of a-keto amide core structure corresponding to "A,"

C. species of N-terminus precursor corresponding to "A," AND

D. species of C-terminus precursor corresponding to "A."

If applicant elects one of Group IV or , applicant is required to elect a species for each of the following categories such that all of the species are compatible with one another:

A. ultimate species (i.e. structure drawing) of drug candidate,

B. species of hydroxyethylamine core structure corresponding to "A,"

C. species of N-terminus precursor corresponding to "A," AND

D. species of C-terminus precursor corresponding to "A."

If applicant elects Group V, applicant is required to elect a species for each of the following categories such that all of the species are compatible with one another:

A. ultimate species (i.e. structure drawing) of one of the drug candidates AND

B. species of a-keto amide core structure corresponding to "A."

If applicant elects Group VI, applicant is required to elect a species for each of the following categories such that all of the species are compatible with one another:

A. ultimate species (i.e. structure drawing) of one of the drug candidates AND

B. species of hydroxyethylamine core structure corresponding to "A."

If applicant elects one of Groups VII-XII, applicant is required to elect an ultimate species (i.e. structure drawing) of improved mechanism based inhibitor.

6. The species are distinct, each from the other, because they have different chemical structures with different chemical, physical, and pharmacological properties and different means of manufacture using different starting materials, method steps, and/or reaction conditions. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon, including any claims subsequently added**. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
18 June 2002

DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600